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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,624	03/16/2004	Anders Lunderqvist	74701	2623
2352	7590	09/30/2005	EXAMINER	
OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/708,624	LUNDERQVIST ET AL.
	Examiner	Art Unit
	Roy D. Gibson	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 19-24 is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Remarks Regarding 35 U.S.C. 112, 6th Paragraph

MPEP 2181 presents the analysis for determining if the 112, 6th paragraph is being invoked. In claim 1, for example, the first paragraph regarding the double lumen balloon does not invoke 112, 6th paragraph, while the third paragraph does. Therefore, the functional language of the first paragraph is considered intended use and the prior art invention need only be capable of meeting the functional language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab (5,624,392).

As to claims 1-7 and 14-16, Saab discloses a double lumen catheter wherein the first and second lumens (Figure 3, inlet lumen # 64 and outlet lumen # 68) are in fluid communication by means of a set of end openings and the second lumen is configured as an inflatable balloon (72); a temperature regulator connected to a reservoir (43) which is surrounded by a heating/cooling device (45), the temperature regulator being configured to regulate the temperature of the fluid; and

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means for circulating the fluid from the reservoir through the catheter (inherently a pump or pressurized fluid means to circulate the fluid) in a closed fluid system via connecting tubing, whereby the balloon is capable of expanding to cover the required area (col. 7, lines 6-18, col. 8, line 17-20, col. 9, lines 9-76, col. 11, lines 36-45, col. 11, line 62-col. 12, line 47 and claims 68-70).

As to claims 10 and 12, Saab discloses maintaining the fluid at a constant temperature, thus inherently providing a temperature sensing means for feedback to the regulator wherein the fluid can be controlled (claim 21) over a broad temperature range (col. 9, lines 57-col. 10, line 10).

As to claims 13 and 17, Saab discloses the catheter is made from a thermoplastic such as PET (col. 8, line 44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 9 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Saab.

As to claims 8 and 9, Saab discloses means to control the flow rates of the circulating fluid, but fails to specifically disclose the flow rate of 200-1000 ml/min

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[Manifold 30 also comprises a fluid inlet port 42 connected to a source, such as reservoir 43, of fluid via a fluid fitting, which may also comprise an inlet valve 41 or other fluid flow control means, and an end seal 44; col. 9, lines 17-20].

However, the examiner maintains that this claimed broad range reveals the lack of critically of the flow rate, thus it would have been obvious to one of ordinary skill in the art to provide a rate as required for achieving the temperature required for the treatment and which would typically fall within the claimed flow rate range and that an alternative means of controlling the pressure (such as a pressure regulating nozzle as is well known in the art) could be utilized.

As to claim 18, the examiner maintains that any combination of tubing, catheters, etc. can be provided in kit form as a convenience to the surgeon, particularly since the items are sealed to prevent contamination.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Nurmi (6,747,930). Saab disclose means for temperature control as detailed above, but, does not disclose the sensor is an IR thermistor. However, Nurmi discloses [It is noted that temperature sensors utilized in system 1 may be of any suitable type (e.g., RTD, IR, thermistor, thermocouple, etc.) to measure the temperature of liquid or any other fluid during system operation; col. 6, lines 29-29].

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Saab, as taught by Nurmi, to utilize an IR thermistor to measure fluid temperature and thereby control the treatment temperature.

Allowable Subject Matter

Claims 19-24 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eshel (5,257,977) discloses a device and method for localized thermal treatment of mammals; Wong et al. (2004/0138728) disclose a device and method for temperature of the brain with a balloon catheter and control of temperature, pressure and flow rate; Dzeng et a. (2003/0210281) disclose a heat exchange catheter for cooling of the esophagus; Balding (2002/0151943) discloses a method and device with a heat exchange catheter for use in the colon; and Neuwirth et al. (4,949,718) disclose a method and device for heating the tissue lining of a body cavity including a balloon with circulating fluid

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Roy D. Gibson
Primary Examiner
Art Unit 3739

September 29, 2005